

REMARKS

Claims 1, 2, 5, 6, 26, 35, 36, and 39-46 are currently under examination. The Examiner has set forth several rejections which are addressed in the order outlined below:

- I. Claims 1, 5, 6, 26, 35, 36 and 42 to 44 are rejected under 35 USC § 112
¶ 1 as allegedly lacking enablement.

I. The Claims Are Enabled

The Examiner states that:

These claims are not enabled for their full breadth because the only polymorphisms within the core promoter region of a human $\alpha 7$ allele corresponding to SEQ ID NO:125 of the instant that [*sic*] have shown to be predictive of a predisposition to schizophrenia in an individual are those recited in claims 40 and 41.

Office Action pg. 2 ¶ 4, and

... the instant application clearly shows that there are known polymorphisms within the core promoter region ... that are not associated with a predisposition to schizophrenia ... Therefore, the instant claims ... constitute nothing more than an invitation to experiment.

Office Action pg 3 ¶ 4. The Applicants disagree because the Examiner has not given due consideration to the complete teachings within the Applicants' specification.

A. Inoperable Embodiments Do Not Effect Enablement

The Examiner is respectfully reminded that a full disclosure of any and all embodiments of a claim need not be presented, and indeed, it is permissible for some of the potential embodiments to be inoperable:

Even if some of the claimed combinations were inoperative, the claims are not necessarily invalid. 'It is not a function of the claims to specifically exclude ... possible inoperative substances. ...'

Atlas Powder Co. v. E.I. Du Pont de Nemours & Co., 750 F.2d 1569, 1576, 224 USPQ 409 (Fed. Cir. 1984). Further, enablement only requires that sufficient guidance be provided within the

specification to allow one having ordinary skill in the art to 'make and use' the claimed embodiment. It is incumbent upon the Examiner to establish a *prima facie* case of lack of enablement (*In re Marzocchi*, 169 USPQ 367, 370 (CCPA 1971)).

B. There Is No Undue Experimentation

The test of enablement is:

... whether one skilled in the art could *make or use* the claimed invention from the disclosures in the patent coupled with information known in the art without undue experimentation.

MPEP 2164.01, citing *United States v. Teletronics, Inc.*, 857 F.2d 778, 8 USPQ2d 1217 (Fed. Cir. 1988); *In re Stephens*, 529 F.2d 1343, 188 USPQ 659 (CCPA 1976), and

The specification is enabling of the claims if "experimentation is ... *routine*, or if the specification provides a *reasonable amount of guidance* on the direction in which the experimentation should proceed to enable the determination of how to practice a desired embodiment of the invention claimed.

Ex parte Forman, 230 USPQ 546 (BPAI 1986)[emphasis added]; see also, *In re Wands*, 8 USPQ2d 1400, 1414 (CAFC 1988). Here, the Applicants have provided complete guidance to one having ordinary skill in the art to: i) identify potential polymorphisms in clinical genetic screens (See, *Applicants' Specification, Examples 18 & 19*); and ii) use statistical tests to determine which potential polymorphisms are related to schizophrenia (See, *Applicants' Specification, Example 20*). In view of these teachings, the Examiner is now required to explain why one having ordinary skill in the art would not be able to employ *routine* experimentation to identify and test other polymorphisms based upon this guidance. Specifically, the Examiner must show, with evidence supported by one having ordinary skill in the art, that the Applicant's techniques requires 'undue experimentation:

For a claimed genus, representative examples together with a statement applicable to the genus as a whole will ordinarily be sufficient if one skilled in the art (in view of level of skill, state of the art and the information in the specification) would expect the claimed genus could be used in that manner without undue experimentation. Proof of enablement will be required for other members of the claimed genus only where adequate reasons are advanced by the examiner to establish that a person skilled in the art could not use the genus as a whole without undue experimentation.


MPEP § 2164.02: Working Example [emphasis added]. Nonetheless, without acquiescing to the Examiner's argument but to further the prosecution, and hereby expressly reserving the right to prosecute the original (or similar) claims, Applicants have amended Claims 1 and 26 to include the single variant and dual variant polymorphisms that are presently recited in the dependent claims. Consequently, Claims 2, 39-41, and 45-46 have been concomitantly canceled. These amendments are made not to acquiesce to the Examiner's argument but only to further the Applicants' business interests, better define one embodiment and expedite the prosecution of this application.

The Applicants respectfully request that the Examiner withdraw the present rejection.

CONCLUSION

Applicants believe the amendments and arguments set forth above traverse the Examiner's rejections and, therefore request that a timely Notice of Allowance be issued in this case. However, should the Examiner believe that a telephone interview would aid in the prosecution of this application, Applicants encourage the Examiner to call the undersigned collect.

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By: 
Thomas C. Howerton
Registration No. 48,650

MEDLEN & CARROLL, LLP
101 Howard Street, Suite 350
San Francisco, California 94105
781-828-9870